We claim :

1. A solid unit dosage form of anhydrous mirtazapine or its pharmaceutically acceptable salts.

2. The dosage form as claimed in claim 1, comprises film-coated tablets of mirtazapine, comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, low-substituted hydroxypropylcellulose and one or more pharmaceutically acceptable excipients.

3. The dosage form as claimed in claim 1, comprises hard, compressed, orally disintegrable tablet dosage form of mirtazapine comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, and one or more non-effervescent excipients.

4. The dosage form of anhydrous mirtazapine as claimed in claim 2, having a particle size distribution (PSD) of 90% particles less than 600 μm, more preferably 90% particles less than 400 μm.

5 The dosage form of anhydrous mirtazapine as claimed in claim 3, having a particle size distribution (PSD) of 90% particles less than 600 μm, more preferably 90% particles less than 400 μm.

6. A process for the preparation of film-coated tablets of mirtazapine, comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, low-substituted hydroxypropylcellulose and one or more pharmaceutically acceptable excipients.

7. A process for the preparation of hard, compressed, orally disintegrable tablet dosage form of mirtazapine comprising anhydrous mirtazapine or its pharmaceutically acceptable salts, and one or more non-effervescent excipients.

8. The dosage form as claimed in claim 3, wherein the non-effervescent excipients comprise binders, dispersing agents, fillers, flavoring agents, sweetening agents, lubricants and glidants.

9. The dosage form as claimed in claim 3, further comprises anhydrous mirtazapine from about 1 to 50 %, and a mixture of non-effervescent excipients comprising from about 10% to 80% of one or more diluents, at least one dispersing agent in an amount of 2% to 15%, from 0% to 15% of one or more binders.

10. The dosage form as claimed in claim 8, wherein the dispersing agent is selected from crosscarmellose sodium, crosspovidone, sodium starch glycolate, sodium carboxymethyl cellulose, hydroxypropyl cellulose, xanthan gum, alginic acid, alginates and carbopols or combination thereof.

11. The dosage form as claimed in claim 8, wherein the diluent is selected from calcium phosphate-dibasic, cellulose-microcrystalline, cellulose powdered, calcium silicate, ploYols such as mannitol, sorbitol, xylitol, maltitol, sucrose and combinations thereof.

12. The dosage form as claimed in claim 8, wherein the binder is selected from methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol, pullulan, starch, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, alginate and plasdone.

13. The dosage form as claimed in claim 8, wherein the lubricant is selected from talc, magnesium stearate, stearic acid or glyceryl behenate preferably magnesium stearate and suitable glidants includes colloidal silicon dioxide and talc.

14. The dosage form as claimed in claim 8, wherein the sweetener is selected from sugars such as sucrose, lactose and glucose; saccharin and salts thereof; mannitol and aspartame.

15. The dosage form as claimed in claim 8, wherein the flavoring agent is selected form strawberry guarana, peppermint, cherry, mint, caramel, raspberry, lemon, orange, tuttifruity, banana, bubble gum, preferably strawberry, guarana, peppermint flavor or combination thereof.

16. The dosage form as claimed in claim 2, wherein the excipients comprise binders, dispersing agents, fillers, lubricants and glidants.

17. The dosage form as claimed in claim 16, wherein the dispersing agent is selected from crosscarmellose sodium, crosspovidone, sodium starch glycolate, sodium carboxymethyl cellulose, hydroxypropyl cellulose, xanthan gum, alginic acid, alginates and carbopols.

18. The dosage form as claimed in claim 16, wherein the diluent is selected from calcium phosphate-dibasic, cellulose-microcrystalline, cellulose powdered, calcium silicate, ploYols such as mannitol, sorbitol, xylitol, maltitol, sucrose and combinations thereof.

19. The dosage form as claimed in claim 16, wherein the binder is selected from methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol, pullulan, starch, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, alginate and plasdone.

20. A process for the preparation of film coated tablets of anhydrous mirtazapine comprising the steps of :

i) sifting mirtazapine through 425 μm sieve, hydroxypropyl cellulose and lactose monohydrate through 850μ sieve separately,

ii) resifting mirtazapine and hydroxypropyl cellulose together through 850μ sieve,

iii) milling the material of step (ii),

iv) rinsing the mill with sufficient quantity of sifted lactose,

v) mixing the material of step (iii) and lactose monohydrate in a rapid mixer granulator and granulating with purified water,

vi) drying the granules in a fluid bed dryer,

vii) sifting the dried granules through 850 μm sieve and collecting the retentions separately,

viii) milling the retentions in a multi mill,

ix) sifting the milled granules of through 850 μ sieve,

x) sifting the extra granular low substituted hydroxypropyl cellulose through 850μ sieve and sifting starch and anhydrous colloidal silicon dioxide together through 850μ,

xi) mixing the sifted low substituted hydroxypropyl cellulose, starch and colloidal silicon dioxide from step (x) with the material of step (ix),

xii) lubricating the material of step (xi) with sifted magnesium stearate,

xiii) compressing the lubricated blend into tablets and

xiv) preparing Opadry coating suspension in water and coating the tablets with coating suspension.

21. A process for the preparation of film coated tablets of orally disintegrating tablets of mirtazapine comprising the steps of :

i) sifting mirtazapine, half the quantity of dispersing agent, binder, diluent through 425 μm mesh,

ii) milling the sifted material of step (i) through multimill,

iii) loading the materials of step (ii) in a rapid mixer granulator and mixing for 15 minutes with impeller at slow speed,

iv) adding purified water over a period of 2-3 minutes with impeller at slow speed

v) kneading the wet mass for 1 minute with only impeller followed by both impeller and chopper at slow speed for 1 min,

vi) drying the wet mass of step (v) at an inlet temperature of 60°C ± 5°C in fluid bed drier,

vii) sifting the dried granules of step (vi) through 600 μm mesh and milling the retentions using multimill with 1.5 mm screen at slow speed / knives forward,

viii) sifting the milled material of step (vii) through 600 μm mesh,

ix) sifting the remaining half of dispersing agent, diluents through 425μm mesh,

x) sifting flavoring agents, sweeteners, glidants, lubricant through 425 μm mesh,

xi) loading the granules of step (viii) in low shear blender,

xii) loading sifted material of step (ix) and (x) except lubricant and blending for 10 minutes,

xiii) adding sifted lubricant in to the low shear blender and blend for 5 minutes,

xiv) compressing the lubricated blend to obtain mirtazapine orally disintegrating tablets.